Pharmaceutical and Medical Packaging News Magazine
PMPN Article Index

Originally Published February 1998

SPOTLIGHT

Blisters in 1998: New Opportunities Emerge

A series of regulatory developments are likely to result in a growing m blisters.

by Karen G. Beagley, Midwest Editor

Are blisters booming? Maybe not at this moment, but there are several regula market developments that are pushing many manufacturers toward blisters. V regulations are expected to expand the blister marketplace, others are likely t companies to reengineer existing blister package designs and employ differen addition, the increased number of clinical trials will probably step up demand Without a doubt, blister packaging activity will be amplified in 1998.

CHILD RESISTANT AND SENIOR FRIENDLY

In June 1995, the U.S. Consumer Product Safety Commission (CPSC; Washing unanimously to issue a final rule modifying the child-resistant packaging test

about us
advertising info
FAQs
site guide
MDL frontpage

Poison Prevention Packaging Act of 1970. "These changes revise the testing m will make closures adult-friendly and easy to open while maintaining their chil The rule change[s] the makeup of test panels[,] substituting senior adults, ag younger adults. This will give a more realistic picture of the ability of normal a child-resistant packaging properly than the current panel of 18 to 45 year olds a statement issued by CPSC.

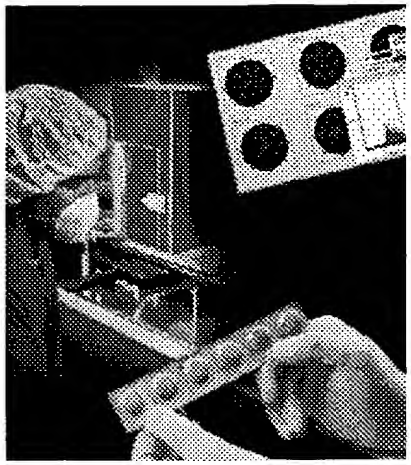


Photo courtesy of Acuity Imaging Inc./Packag Inc.

The big news now is that as of January 22, 19 began compliance testing using the new senic protocol, which means CPSC representatives packages off the shelves or make establishme "This was an important ruling," says Ken Gile for CPSC. "Twenty percent of the children bei pharmaceuticals were [poisoned by] their gra medicines. The older adult population were n opening and then closing their prescription m

So what can manufacturers do if their blister resistant but can't be opened by the senior te "Manufacturers that have claimed child-resistant packaging have all the child Richard Ward, vice president and director of consumer product testing, Perritt (Hightstown, NJ). "Now companies have to deal with the senior test panel. Ch directions on the package to read 'Open with scissors' or 'Cut here' enables th be opened by the senior test panel. We do not recommend using a scissors ico package showing where to cut. A child will recognize that icon, go get the scis able to get into the blister. We advocate 'Say it, don't show it.'"

Of course, blister packages will need to be reengineered so they can be cut op scissors. "I think we need a newer, better design giving an area where the per blister and get to the medicine," Ward says.

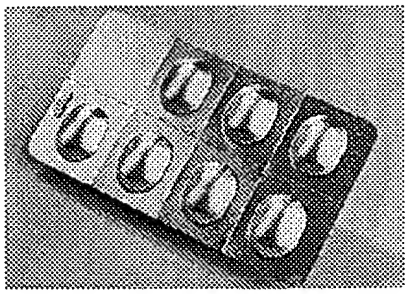
"Over-the-counter drugs are increasingly coming out in blisters because of the and convenience factors," says Dan Gerner, president, Packaging Coordinator (Philadelphia).

"There has been a trend toward child resistant even before it was dictated," sa Conlon, vice president of sales, Romaco Inc. (Morris Plains, NJ). "Peel-and-pu child resistant and now the big issue is to make them senior friendly."

STABILITY TESTING REQUIREMENTS

This past January 1, the International Conference on Harmonisation's (ICH) Te Requirements for the Regulation of Pharmaceuticals for Human Use took effec requirements deal with stability testing for packages and have been adopted b Specifically, the guidelines change the accelerated stability test from 3 month relative humidity to 6 months at 40°C, 75% relative humidity.

The blister industry is taking a variety of approaches to ensure that products v the more stringent testing procedures. "We are seeing a trend toward using hi films that will meet these stability testing guidelines," explains Knud A. Christi director of pharmaceutical films at Klöckner Pentaplast of America (Princeton, testing conditions are much more severe now. The same drug that passed bef necessarily pass in the same package under the new stability testing."



An all-aluminum blister package from Teich Pa

Increasingly, companies are seeking out newer materials that can hold up to t rigorous testing procedures. "We are seeing pharmaceutical companies lookin seriously at cold-formable foil to meet the more demanding tests," says Dave healthcare sales manager, Hueck Foils LLC (Manasquan, NJ).

Burt Zirin, the president of Teich Packaging Inc. (Northbrook, IL), comments: usage of high-barrier cold forming aluminum for moisture-sensitive drugs to n stability-testing guidelines. There are lots of good materials available to meet

However, the IHC requirements are only some of the factors driving companie alternative materials for blister packaging. "Pharmaceutical companies are cha to meet ICH's guidelines and for other reasons such as price and ease of use. I different laminations is becoming more popular," says Bob Misher, executive v Blis-Tech Inc. (Fairview, NJ). "Foil/foil packages have been big in Europe and coming here."

EUROPEAN MARKET

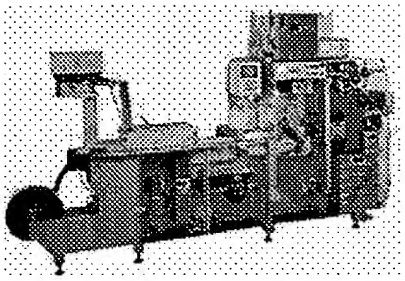
The European market for blisters is larger than that in the United States. "The market uses more blisters than we do, whether they're for prescription or over says Hugh Lockhart, professor, Michigan State University School of Packaging MI). "They use more-opaque materials, which they claim are less attractive to culture has been more accepting of blisters as the preferred method of packag

The European community also has stronger environmental reasons for using b manufacturers are penalized for introducing excessive material into the systen blister is cut to a minimal size," says Tom McMurray, director of package engi Warner-Lambert (Morris Plains, NJ). "They are just more frugal in their use of Blisters come in the preferred multiple for the specific country. For example, I multiples of seven."

Another environmental aspect of the widespread use of blisters in Europe is th from PVC. "Europe uses polypropylene for blisters; they feel very strongly abo for undesirable by-products you can get as a result of burning PVC," explains

CLINICAL TRIALS

Another growth area for blisters is clinical trials. With the increasing incidence trials, many of which require complex regimens, more pharmaceutical compar employing blisters. "We use blisters from a convenience and compliance stand Gary Puzio, clinical supplies manager, Phase IV research group, Schering-Plou NJ). "For a dose range study where the patient is taking four tablets a day or only way to do it is in a blister. It is hard to tell a patient to take one tablet fro then one from this bottle, etc. With a blister, all the medication is there, easily



Romaco Inc.'s blister packaging machine can than 300 blister packs per minute.

One issue that clinical trial companies are considering is whether blister packa subject to CPSC's child-resistant/senior-friendly regulations. "I have talked wi they have said that if the package goes into the person's home, then it is subj regulations as other packaging," says Stan Johnson, chief of integrated quality VA Cooperative Studies Program, Clinical Research Pharmacy Coordinating Ce (Albuquerque). "During most of our studies, the patients take the medications them. For a limited clinical trial it is not worth the time and expense of conduc for child-resistant and senior-friendly features. Previously, the FDA requireme provision absolving clinical trials from some of the regulations. With CPSC, the seem to be the latitude we need."

According to CPSC, all medications that end up in a home environment are sul child-resistant/senior-friendly regulations. "The manufacturer of the package i for the testing to ensure that it is in compliance," says CPSC's Giles. "Pharmac be in child-resistant packages, which also must meet the senior-friendly guide doctor or patient specifically asks for a non-child-resistant package."

IRON SUPPLEMENTS AND THE METHAMPHETAMINE CONTROL ACT

Two regulatory developments relating to iron supplements and methamphetar manufacturing may affect future growth of blister packaging. FDA's final rule c titled *Iron-Containing Supplements and Drugs: Label Warning Statements and Packaging Requirements* (21 CFR parts 101, 111, and 310), took effect on July provision of the ruling calls for unit-dose packaging for iron-containing produc 30 mg or more of iron per dosage unit.

"There have been some companies that have had to take iron products off the because they were not in unit-dose packaging," says Matt Neumann, vice pres operations, Uhlmann Packaging Systems (Towaco, NJ). "We are seeing a mov blisters having to be in compliance. Even though this ruling is already in effect companies did not have the time to get their iron into blisters."

On October 3, 1996, President Clinton signed into law the comprehensive Met Control Act of 1996. The law broadens control over certain chemicals used in t of methamphetamine, increases penalties for the trafficking and manufacture methamphetamine and listed chemicals, and expands regulatory controls to ir distribution of certain lawfully marketed products that incorporate ephedrine, pseudoephedrine (PSE), and phenylpropanolamine (PPA).

The law subjects transactions involving PSE and PPA to the registration, recor reporting requirements of the Controlled Substances Act. The law creates a sa exemption for the retail sale of ordinary over-the-counter products that contai according to a statement from the Nonprescription Drug Manufacturers Associ Washington, DC).

"In order to be included in the safe harbor, the product must meet two require package must contain not more than 3 g of the base ingredient, and 2) the pr in blister packs of not more than two tablets per blister (unless use of the blist

technically impossible, such as for liquids). For those products not packaged ir with the safe harbor exemption as of Oct. 3, 1997, pharmaceutical retailers ar register with the Drug Enforcement Administration if they sell more than 24 g transaction and to keep records of such transactions," according to NDMA's sta

"Basically, what this means is that if a retailer wants to avoid all the paperwor registering, the retailer should sell the products in blister packaging," says Joe vice president and director of public affairs, NDMA. "The law is designed to stc unscrupulous manufacture of an illegal drug from these substances. This woul difficult to have to open each blister package to get the required amount of dr

CONCLUSION

This year will definitely bring both challenge and opportunity to companies usi packaging. Packaging engineers have been called upon to develop creative sol meeting CPSC's child-resistant, senior-friendly requirements. With additional r developments, such as the ICH testing guidelines and the rule on iron supplen likely to see more blisters, along with the use of innovative materials and desi